(1) Submitter Information
Name: Platinum Services, Inc.
Address: 115 Boise Street, DeQuincy, LA 70633
Telephone Number: 337-786-2911
Contact Person: Nancy Street, 302-836-9919

(2) Names
Trade: SeraGard™ Injection Patch
Common Usual Name: SeraGard™ Injection Patch
Classification Name: Accessory for Hypodermic Needle

(3) Classification, Panel
Class 1, 79FRO

(4) Predicate Devices
(a) Sof-Set needle, manufactured by Minimed Technologies.
(b) Patch Band-Aid,, manufactured by Johnson and Johnson

(5) Description
The SeraGard™ Injection Device is a small self-adhesive Patch, resembling a round Band-Aid. The Patch is placed over the site of the injection (held in place by adhesive backing), and the needle punctures the center of the Patch before entering the skin. The Patch is discarded after hemostatis occurs.

(6) Intended Use
The SeraGard™ Injection Patch is intended to contain sera during a hypodermic injection - it is not intended to act as a dressing. The Patch is indicated for use during subcutaneous or intramuscular injection procedures to contain blood and isolate the wound.

(7a) Predicate Devices
The SeraGard™ Injection Patch has as predicate devices the familiar Band-Aid, manufactured by Johnson and Johnson, which is similar in construction and materials, and the Sof-Set needle, manufactured by Minimed Technologies, which has the same intended use and reduces the possibility of infection by a similar technology.

(7b) Testing
The SeraGard™ Injection Patch uses materials which have been previously used in dressings and which have been extensively tested by the suppliers. Test data are included in the submission. The SeraGard™ Injection Patch has also undergone a clinical trial for efficacy, for biological reactions, and for professional and patient acceptance, using volunteer patients and injections of sterile saline. All results were satisfactory.

These tests all show that the SeraGard™ Injection Patch is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2000

Ms. Nancy Street
Director of Process Engineering
Platinum Services, Incorporated
115 Boise Street
DeQuincy, Los Angeles 70633

Re: K001240
Trade Name: SeraGard™ Injection Patch
Regulatory Class: I
Product Code: KGX
Dated: April 16, 2000
Received: April 18, 2000

Dear Ms. Street:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Center for Devices and Radiological Health

Page 1 of 1

510(k) Number (if known): K001240

Device Name: SeraGard™ Injection Patch

Indications for Use:

The SeraGard™ Injection Patch is a self-adhesive pad intended to contain blood during subcutaneous or intramuscular injections.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

Patricia Cascade

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001240